APR 2 1 2006

K060573

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA and 21 CFR 807.92.

1. **Submitter's name, address, telephone number, contact person, and date summary prepared:**

   a. Submitter: Vascular Control Systems, Inc.
   32236-F Paseo Adelanto
   San Juan Capistrano, CA 92675
   (949) 488-8700

   b. Contact Person: Kathleen Roberts
   RA/QA Manager
   (949) 488-8700 ext. 115

   c. Date Summary Prepared: April 5, 2006

2. **Name of device, including trade name and classification name:**

   a. Trade/Proprietary Name: Burbank Tenaculum

   b. Classification name: Uterine Tenaculum (21 CFR §884.4530)

3. **Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**

Company:	Vascular Control Systems, Inc.
Device:	Burbank Tenaculum
510(k):	K030078
Date Cleared:	January 24, 2003

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

   The Burbank Tenaculum is a ring-handled instrument with a tooth at the distal end of one arm and a guiderod attached to the distal end of the other arm. The proximal end of the guiderod is threaded to guide insertion of the Vascular Control Systems *flo*stat Clamp into the vagina and secure the Clamp in place.

   A uterine sound, at the distal end of the guiderod, is intended for insertion through the cervical opening into the uterine cavity.

5. **Statement of intended use:**

The Burbank Tenaculum is an accessory used in conjunction with Vascular Control Systems' *flo*stat™ Clamp. The device is intended to seize and hold the cervix and secure the *flo*stat Clamp in place, during audible Doppler procedures.

This Tenaculum is only indicated for use with the *flo*stat Clamp and Transvaginal Doppler Probe for bilateral uterine artery detection and temporary control of bleeding during conservative gynecologic surgery such as laparoscopic myomectomy.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

Both devices are ring-handled with ratchet closure for seizing and holding the cervix. Both devices are designed with a tooth for seizing and holding the cervix and are equipped with a mechanism to hold an ultrasound guided clamp. The new materials used in the modified Burbank Tenaculum include glass-filled nylon not part of the original design.

7. **Brief summary of nonclinical tests and results:**

The Burbank Tenaculum has been designed and tested per design control procedures and was found to meet its product specifications. The Burbank Tenaculum does not raise new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 2 1 2006

Vascular Control Systems, Inc.
% Mr. Tamas Borsai
Program Manager, Third Party Review Program
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K060573
Trade/Device Name: Burbank Tenaculum
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecology specialized manual instrument
Product Code: HDC
Regulation Number: 21 CFR §870.4450
Regulation Name: Vascular Clamp
Product Code: DXC
Regulatory Class: II
Dated: April 6, 2006
Received: April 7, 2006

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K060573

Device Name: Burbank Tenaculum

Indications for Use:

The Burbank Tenaculum is an accessory used in conjunction with the Vascular Control Systems *flo*stat™ Clamp. The device is intended to seize and hold the cervix and to hold and secure the *flo*stat Clamp in place, during audible Doppler procedures.

This Tenaculum is only indicated for use with the *flo*stat Clamp and Transvaginal Doppler Probe for bilateral uterine artery detection and temporary control of bleeding during conservative gynecologic surgery such as laparoscopic myomectomy.

Prescription Use _X_ AND/OR Over-The-Counter-Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060573